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World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

1339692

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 29, 2005

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: *60/573,134*
FILING DATE: *May 21, 2004*
RELATED PCT APPLICATION NUMBER: *PCT/US05/18639*

Certified by

Jon W. Dudas

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

PTO/SB/16 (10-01)
Approved for use through10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.	EL988370325US

17314 US 150 052104

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Lawrence	Solomon	7810 Alton Villa CT. Boca Raton, FL 33433

☑ *Additional inventors are being named on the* 1 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

EXACTLY DIVIDABLE, LAYERED, SCORED TABLET

22161 U.S. PTO 60/573184 052104

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 11
☑ Drawing(s) *Number of Sheets* 1
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☐ Other (specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.
☑ A check or money order is enclosed to cover the filing fees
☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 08-1540
☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____

TYPED or PRINTED NAME Nicholas P. Chiara

TELEPHONE (212) 302-8989

Date 05/21/2004

REGISTRATION NO. *(if appropriate)* 52,737

Docket Number: 1322-013

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

PROVISIONAL APPLICATION COVER SHEET
Additional Page

PTO/SB/16 (02-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Docket Number	1322-013

INVENTOR(S)/APPLICANT(S)		
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Allan S.	Kaplan	7011 Mallorca Cresent Boca Raton, FL 33433 USA

Number 2 of 2

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UNITED STATES PATENT APPLICATION

(PROVISIONAL)

of

Lawrence Solomon

and

Allan Kaplan

EXACTLY DIVIDABLE, LAYERED, SCORED TABLET

1322-013

EXACTLY DIVIDABLE, LAYERED, SCORED TABLET

FIELD OF THE INVENTION

The invention is concerned with the making of a tablet dosage form for the administration of pharmaceuticals or other materials. The novel scored tablets of the invention may be readily and accurately separated into separate parts which contain predetermined quantities of ingredients.

BACKGROUND OF THE INVENTION

It is well known to provide tablets for handling pre-measured quantities of materials which allow consumers to use various materials without the need to use expensive and cumbersome measuring devices. Tablets have been used to prepare measured amounts of herbicides, pool-treating chemicals, pigments, pharmaceuticals and other solid products which are used in measured amounts. It is common with these tablets to form the tablet with an indentation, commonly referred to as a "score," that is sized and positioned to enable an end user to break the tablet into one or more components. It is recognized that heretofore a method of producing complete, accurate, and predictable division of active ingredient(s) in a tablet has not been disclosed.

Many drugs require dosage adjustments. Tablets such as warfarin are scored and are highly potent and patients are frequently advised by physicians to divide warfarin tablets to effect dosage adjustments. If a patient divides a tablet of this drug, the result is likely to not be an exact division of the tablet. The resultant imprecise dosing may cause adverse medical consequences.

SUMMARY OF THE INVENTION

The present invention is concerned with a dosage form containing at least two layers, in which at least one layer is conveniently and precisely dividable into sections, by means of one or more scores that extend substantially to an adjacent layer. The dosage form preferentially comprises a layered structure composed of two adjacent layers, one containing the active ingredient or mixture of active ingredients (layer 2) and the other containing either an inert substance or one or more active substances (layer 4), wherein layer 2 is fully breakable in an exact, predetermined manner (such as into two equal halves), whereas layer 4 does not break fully evenly. The reason that layer 2 can be broken into exactly equal halves is that it has a score that extends A) substantially completely into layer 4 or B) substantially to layer 4. Thus, if the tablet is broken, the break will take place A) only or B) substantially only in layer 4.

The invention also includes the method of administering a pharmaceutical to a patient which comprises administering a dosage form comprising a layered structure having two or more layers, wherein the first layer comprises active ingredient(s) and the second layer comprises inert ingredients, or one or more active ingredients. Said first layer being completely scored to allow it to separate precisely into two or more parts of predetermined amount of active ingredient(s)when the tablet is broken through the score(s).

The invention further contemplates that the method of breakage may be manual, but manual breakability is not required if mechanical breakage may be conveniently

accomplished by ordinary means such as by utilizing a commercially-available tablet cutter, a kitchen knife, or a penknife ("manual or mechanical").

It is contemplated that should it be desired that layer 4 contain active drug, and there be physical incompatibility between any component of layer 2 with layer 4, a thin separating layer, as is well known in the art, may be placed between layers 2 and 4 that is mutually compatible with each layer. In that case, the score of layer 2 will extend substantially at least to the separating layer (not shown), and possibly into layer 4. For convenience, the term "inert layer" when applied to a two-layer tablet hereafter, is intended to encompass the circumstance in which layer 4 as used above contains active drug(s) and is not inert.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Fig. 1 is a side view of a cross-section of a two-layer scored tablet according to the invention, which shows an embodiment in which the score terminates at the interface of the active and inert layers.

Fig. 2 is a side view of a cross-section of a two-layer scored tablet according to the invention, which shows an embodiment in which the score extends through the active layer and into the inert layer.

Fig. 3 is a side view of a cross-section of a two-layer scored tablet according to the invention, which shows an embodiment in which the score extends through the interface of the active layer into the inert layer and a reinforcing ridge has been formed as part the inert layer.

Fig. 4 is a top view of a two-layer scored tablet according to the invention which has been scored into four sections.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is particularly useful when precise dosing is important and patients undergo dosage adjustments from time to time.

Examples of these drugs includes, nonexclusively, warfarin, digoxin, digitoxin, and l-thyroxine.

As shown in Fig. 1, the active layer 2 is placed against layer 4 and score 6 is created to extend completely through the active layer to but not into the inert layer. This arrangement allows the active layer to be divided into two exact sections because the break occurs at the interface of the inert and the active layers in such a manner that the portions of the tablet containing the active drug are completely and exactly separable. While this embodiment is a tablet in which the active layer is divided into two parts, it is also possible to provide three or more scores that extend up to or into the inert layer.

Fig. 2 varies from Fig. 1 in that the score extends into layer 4.

Fig. 3 varies from Fig. 2 in that a reinforcing ridge 12 is created as part of layer 4 in register with ridge 6 to help protect the tablet from breakage.

Fig. 4 is a top view of an embodiment of the invention in which the tablet is scored to provide sections 14, 16, 18 and 20. Shading 22 is used to show the sloping

walls of the scores while line 24 shows the bottom of the score mark.

The drawings illustrate the scores as being V-shaped but the shape of the scoring profile is not critical to the scope of the invention, and the invention includes scores having any type of profile that allow the precise division of the active layer without regard to the accuracy of the division of the remainder of the tablet.

It is contemplated that the different layers may either have the same or different colors.

The tablets may be made using conventional ingredients such as those disclosed in standard textbooks such as Remington's Pharmaceutical Sciences, 17th Ed.(1985) pp. 1603-1632, which are incorporated by reference.

The technique of making the tablets may comprise first feeding a granulation of the inert component into a tablet die and tamping the granulation into place. Then, a granulation of the active drug is placed on top of the tamped inert granulation and an embossed die having the reverse configuration of a score mark(s) is applied to the top of the granulation of the active ingredient to form the tablet with a groove or grooves (or score(s)) being pressed into the active layer by the embossed die as described above.

As examples, layer 2 may contain one or more of the following, and layer 4 may be substantially inert or may contain one or more of the following as well.

The following list discloses a variety of active pharmaceutical ingredients which could be given singly or in combination either in layer 2 or layer 4, with layer 4 in the invention's more preferred embodiment containing no

active drug. These examples are a small subset of the possible examples, which comprise substantially every tabletable drug or drug combination that has existed, is in existence, or that may come to exist.

HYPOGLYCEMIC AGENTS:
Thiazolidinediones: Pioglitazone, rosiglitazone
Sulfonylureas: Glyburide, glipizide, glimepiride, chlorpropamide
Biguanides: Metformin
Meglitinides: Nateglinide, repaglinide
Glucosidase inhibitors: Acarbose, miglitol

ANTIHYPERTENSIVE AGENTS:
Beta-blockers:
Acebutolol, atenolol, bisoprolol, celiprolol, metoprolol, mebivolol, carvedilol (a mixed alpha-beta blocker), nadolol, oxprenolol, penbutolol, pindolol, propranolol, timolol, betaxolol, carteolol,

Calcium antagonists (calcium-channel blockers):
Nifedipine, amlodipine, verapamil, diltiazem, nisoldipine, felodipine, isradipine, lacidipine, lercanidipine, nicardipine, manidipine

Thiazide-type diuretics (with or without potassium-retaining diuretics such as triamterene, amiloride, spironolactone, etc.):
Hydrochlorothiazide, chlorothiazide, cyclopenthiazide, polythiazide, bendrofluazide, hydroflumethiazide, chlorthalidone, indapamide, methylclothiazide, metolazone

Angiotensin converting enzyme inhibitors:

Captopril, enalapril, lisinopril, ramipril, trandolapril, quinapril, perindopril, moexipril, benazepril, fosinopril

Angiotensin receptor blockers:
Losartan, valsartan, candesartan, telmisartan, eprosartan, irbesartan

High-ceiling (loop) diuretics (with or without potassium-retaining diuretics such as triamterene, amiloride, spironolactone, etc.):
Furosemide, torsemide, ethacrynic acid, bumetamide

Aldosterone antagonist diuretics:
Spironolactone, eplerenone

Alpha-blockers:
Doxazosin, terazosin, prazosin, indoramin, labetolol (a mixed alpha-beta blocker)

Central alpha-agonists:
Clonidine, methyldopa

Imidazoline:
Moxonidine

Direct vasodilators:
Hydralazine, minoxidil
Adrenergic neuronal blocker:
Guanethidine

LIPID-MODIFYING AGENTS:

A) Statins:
Lovastatin, simvastatin, pravastatin, rosuvastatin, atorvastatin, fluvastatin

B) Fibrates:
Clofibrate, bezafibrate, fenofibrate, gemfibrozil, ciprofibrate

C) Others:
Ezetimide, niacin, acipimox

While certain preferred and alternative embodiments of the invention have been set forth for purposes of disclosing the invention, modifications to the disclosed embodiments may occur to those who are skilled in the art. Accordingly, this specification is intended to cover all embodiments of the invention and modifications thereof which do not depart from the spirit and scope of the invention.

Claims:

1. A dosage form comprising a structure consisting of at least two stratified layers of different composition, wherein a layer comprises one or more active ingredients and is exactly and predictably dividable by a scoring pattern placed into or substantially to an adjacent layer which is substantially an inert layer, or contains one or more active ingredients.

2. A dosage form as defined in claim 1 wherein the score extends completely through the active layer and ends at the interface between the active layer and the inert layer.

3. A dosage form as defined in claim 1 wherein the score extends completely through the active layer and past the interface between the active layer and the inert layer so that the score ends in the inert layer.

4. A dosage form as defined in claim 1 wherein the unscored or incompletely scored layer contains active drug or drugs.

5. A dosage form as in claim 4 wherein an inert separating layer exists and the unscored or incompletely scored layer contains active drug(s).

6. A method of administering a pharmaceutical to a patient which comprises administering a dosage form as in claim 1, wherein a first layer comprises one or more active ingredients and is exactly and predictably dividable by a scoring pattern placed into or substantially to an

adjacent layer which is substantially an inert layer, or contains one or more active ingredients.

7. A method as defined in claim 6 wherein the score in the dosage form extends completely through the active layer and ends at the interface between the active layer and the inert layer.

8. A method as defined in claim 6 wherein the score in the dosage form extends completely through the active layer and past the interface between the active layer and the inert layer so that the score ends in the inert layer.

9.A method as defined in claim 6 wherein the unscored or incompletely scored layer of the dosage form contains active drug or drugs.

10. A method as defined in claim 6 wherein the dosage form has an inert separating layer and the unscored or incompletely scored layer contains active drug.

ABSTRACT

A dosage form comprising a structure consisting of at least two stratified layers of different composition, wherein a layer comprises one or more active ingredients and is exactly and predictably dividable by a scoring pattern placed into or substantially to an adjacent layer which is substantially an inert layer, or contains one or more active ingredients.

1322-013

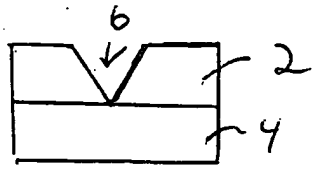

FIG. 1

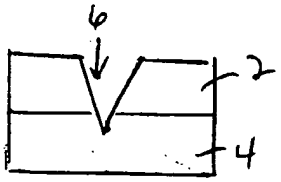

FIG. 2

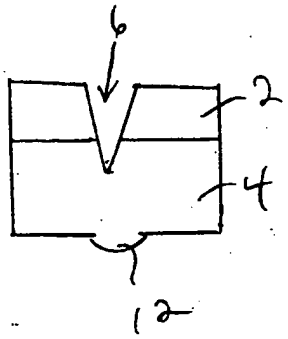

FIG. 3

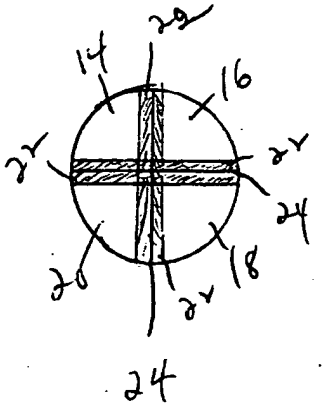

FIG. 4

Copy for (DO-EP) 31
PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92*bis*.1 and Administrative Instructions, Section 422)

To:

COSTIGAN, James, V.
Hedman & Costigan, P.C.
1185 Avenue of the Americas
New York, NY 10036
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*
16 November 2006 (16.11.2006)

Applicant's or agent's file reference
1322-034 PCT

IMPORTANT NOTIFICATION

International application No.
PCT/US2005/018639

International filing date *(day/month/year)*
23 May 2005 (23.05.2005)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

Name and Address
SOLAPHARM, INC.
1000 S Pine Island Road
Suite 230
Plantation, FL 33324
United States of America

State of Nationality: US
State of Residence: US
Telephone No.
Facsimile No.
Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☒ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address
ACCU-BREAK PHARMACEUTICALS, INC.
1000 S Pine Island Road
Suite 230
Plantation, FL 33324
United States of America

State of Nationality: US
State of Residence: US
Telephone No.
Facsimile No.
Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the International Preliminary Examining Authority
☒ the designated Offices concerned
☐ the elected Offices concerned
☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
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PATENT COOPERATION TREATY

PCT

10/598?16

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 1322-034 PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2005/018639	International filing date *(day/month/year)* 23 May 2005 (23.05.2005)	Priority date *(day/month/year)* 21 May 2004 (21.05.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ACCU-BREAK PHARMACEUTICALS, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 21 November 2006 (21.11.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Nora Lindner e-mail: pt02@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
JAMES V. COSTIGAN
HEDMAN & COSTIGAN, P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	21 SEP 2005
Applicant's or agent's file reference 1322-034 PCT	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/18639	23 May 2005 (23.05.2005)	21 May 2004 (21.05.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61K, 9/20, 9/44, 9/22 and US Cl.: 424/464, 467, 468

Applicant

SOLARPHARM, INC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-8300	01 September 2005 (01.09.2005)	David Vanik Telephone No. (571) 272-3104

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/18639

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into ____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/18639

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 3-5, 10, 12-15, 18-26, 32-38, 42	YES
	Claims 1-2, 6-9, 11, 16-17, 23, 27-31, 43-44	NO
Inventive step (IS)	Claims 3-5, 10, 12-15, 18-26, 32-38, 42	YES
	Claims 1-2, 6-9, 11, 16-17, 23, 27-31, 43-44	NO
Industrial applicability (IA)	Claims 1-44	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-2, 6-9, 11, 16-17, 23, 27-31,43-44 lack novelty under PCT Article 33(2) as being anticipated by US 5,738,874 ('874).

'874 disclose pharmaceutical tablets comprising three separate layers (abstract and Figures 1-2). Said tablets comprise both an immediate release and sustained release component (abstract). According to '874, two of the three layers comprise one or more drugs (abstract; Examples 1-6; Claims 1-7). The layers may comprise either the same or different drug (abstract; column 5, lines 14-30; Examples 1-6). It should be noted that the examiner gives no patentable weight to the order of the layers in the instant claim set. As written, this appears to be an arbitrary parameter. It is the examiner's position that ketoprofen, a well-known arthritic medicine, is present in an amount sufficient to treat pain.

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by US 3,336,200 ('200).

'200 disclose tablets comprising two or more segments further comprising drugs (Figures 1-3 and column 2, lines 24-26). The tablets may be either sustained or immediate release (Example 2).

Claims 3-5, 10, 12-15, 18-26, 32-38, 42 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest tablets with the limitations set forth in the instant claims 3-5, 10, 12-15, 18-26, 32-38, 42.

Claims 1-44 meet the criteria set out in PCT Article 33(4), and thus contain industrial applicability because the subject matter claimed can be made or used in industry.